

A Company of Sysmex Group



HYPHEN BioMed 155 rue d'Eragny 95000 Neuville-sur-Oise France

CERTIFICATE OF ANALYSIS

Product Description:

BIOPHEN EDOXABAN CALIBRATOR

Product Code:

226501

Lot No.:

FD08591E

Expiration date:

2026-10-13

Components	Quantity	Lot	Expiration Date
CAL 1	4 vials	FD0859aa1E	2026-10-13
CAL 2	4 vials	FD0859ab1E	2026-10-13
CAL 3	4 vials	FD0859ac1E	2026-10-13

Analytical Data	Specification	Result
Concentration	CAL 1 : ≤ 40 ng/ml CAL 2 : 200 -300 ng/ml CAL 3 : 400 -600 ng/ml	0 ng/ml 238 ng/ml 487 ng/ml
Linearity and accuracy of calibration with values assigned	$\label{eq:R2} R^2 \geq 0.98$ Measured values for controls in acceptance ranges	PASS PASS

This is to certify that above product has been produced and passed the inspection according to specifications of HYPHEN BioMed.

Quality Control Approval

Date of Approval:

16 MAI 2024

Quality Control Manager:

S. LECOURT